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Ensysce Biosciences Announces Successful Meeting with FDA for PF614-MPAR, a Next Generation Opioid with Overdose Protection

~ PF614-MPAR program receives FDA guidance ~

SAN DIEGO, CA / ACCESSWIRE / February 21, 2024/ Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage company applying transformative chemistry to improve prescription drug safety, is providing an update following its recent meeting with the Food and Drug Administration (FDA) regarding its second product, a 'Next Generation' opioid analgesic with overdose protection, PF614-MPAR.

The meeting focused on the Company's non-clinical program for the combination product that is designed for the treatment of severe pain. The FDA provided helpful feedback and advice on non-clinical studies that are required for eventual new drug application (NDA) submission and approval. The guidance will aid in streamlining the development plans for this innovative drug candidate to bring PF614-MPAR to the market as quickly as possible.

As recently announced, PF614-MPAR was granted Breakthrough Therapy designation by the FDA which allows more frequent meetings and access to FDA experts. PF614-MPAR is a combination product of PF614, a trypsin-activated abuse protection (TAAP) oxycodone prodrug, and a trypsin inhibitor, nafamostat. PF614, Ensysce's lead drug candidate and the base for PF614-MPAR, has entered Phase 3 clinical development following its demonstration of efficacy and safety in recent trials and a recent End of Phase 2 meeting with the FDA.

The clinical data demonstrated that PF614 delivers oxycodone with the benefit of a longer half-life than products currently on the market, providing what Ensysce believes will be more sustained pain relief with reduced adverse effects that occur following repeat dosing of shorter-acting opioid analgesics. PF614-MPAR takes the product to the next level with overdose protection, by the addition of nafamostat which "switches off" the release of oxycodone when too many doses are ingested simultaneously. This approach to drug safety is first-in-class and has the potential to beneficially impact many lives.

"We are appreciative of guidance provided by the FDA to help us develop PF614-MPAR," commented Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce. "The fact that we have been granted Breakthrough Therapy status is a sign of the critical nature of this product. As a country, we are still losing two Americans every hour to opioid prescription overdose. My team now has an approach to attack this problem with what we believe will be a game-changing opioid analgesic that has the potential to reduce opioid overdoses while providing better control of severe acute and chronic pain. We also believe that our approach can

benefit both new and existing drugs with improved therapeutic outcomes and reduced abuse."

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage company using its proprietary technology platforms to develop safer prescription drugs. Leveraging its Trypsin-Activated Abuse Protection (TAAP™) and Multi-Pill Abuse Resistance (MPAR®) platforms, the Company is developing unique, tamper-proof treatment options for pain that minimize the risk of both drug abuse and overdose. Ensysce's products are anticipated to provide safer options to treat patients suffering from severe pain and assist in preventing deaths caused by medication abuse. The platforms are covered by an extensive worldwide intellectual property portfolio for a wide array of prescription drug compositions. For more information, please visit www.ensysce.com.

Definitions

TAAP: trypsin activated abuse protection - designed to protect against prescription drug abuse.

MPAR: multi-pill abuse resistance - designed to protect against abuse and accidental overdose.

Forward-Looking Statements

Statements contained in this press release that are not purely historical may be deemed to be forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Without limiting the foregoing, the use of words such as "may," "intends," "can," "might," "will," "expect," "plan," "possible," "believe" and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinic and not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Ensysce will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. All forward-looking statements are based on estimates and assumptions by Ensysce's management that, although Ensysce believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Ensysce expected. In addition, Ensysce's business is subject to additional risks and uncertainties, including among others, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from preclinical studies and clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Ensysce's product candidates; the availability or commercial potential of product candidates; the ability of Ensysce to fund its continued operations, including its planned clinical trials; the dilutive effect of stock issuances from our fundraising; and Ensysce's and its partners' ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in Ensysce's most recent quarterly report on Form 10-Q and current reports on Form 8-K, which are available, free of charge, at the SEC's website at www.sec.gov. Any forward-looking statement speaks only as of the date on which it was made. Ensysce

undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required under applicable law.

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